

Remarks

Status of the Application and the Present Response

Prior to entry of the present Response, claims 1-9 and 11-76 were pending in the application, with claims 34-76 being withdrawn from the application as directed to non-elected inventions. Claims 1, 2, 4-6, 8, 9, and 11-33 were rejected as allegedly lacking written description. Claims 3 and 7 were objected to. The Examiner indicated that these two claims are allowable if rewritten in independent forms. Applicants thank the Examiner for withdrawing rejections under 35 U.S.C. §§ 102 and 103 that were made in the previous Office Action.

With entry of the instant response, claims 14, 20, 21, and 75-76 have been canceled without prejudice, and claims 1, 15, 29-32, 56, 63, 64, 67, 71, and 73 have been amended. Claim 1 has been amended to specify that the solubility responsive promoter is a prokaryotic promoter. Claims 56, 63, 64, 67, 71, and 73 have been similarly amended. Claim 15, which originally depends from claim 14, has been amended to depend from claim 1 due to cancellation of claim 14. In addition, claims 29-32 have been amended to depend from claim 28 and to further define the "species" element in claim 28. The additional elements introduced in these claims parallel that in claims 15-18, respectively. Support for the amendments made herein is replete in the specification, e.g., in the original claims. These amendments do not introduce new matter. Unless otherwise indicated, the claim amendments have been made to improve clarity or to expedite prosecution of the subject application, and should not be construed as acquiescence of any ground of rejections.

The following remarks address issues raised in the instant Office Action.

Double Patenting

Claim 1 was provisionally rejected by the Examiner under the judicially created doctrine of obviousness-type double patenting in view of certain claims in co-pending applications 10/127,078 and 09/991,499.

From Applicants' docketing system, Applicants cannot find the existence of "co-pending application No. 09/991,499." Based on the limited information retrieved

from USPTO PAIR system, it appears that "co-pending application No. 09/991,499" is identical to the subject application. Applicants question whether the USPTO might have mistakenly assigned two different serial numbers to the subject application. Clarification from the Office regarding this matter will be greatly appreciated.

With regard to co-pending Application No. 10/127,078, as noted in the Office Action, the alleged conflicting claims have not in fact been granted. Therefore, Applicants with address the instant rejection once claims in the co-pending applications have been issued.

Rejection under 35 U.S.C. § 112 - Written Description

The instant Office Action maintained the rejection of claims 1, 2, 4-6, 8, 9, and 11-33 under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. The rejection appears to have be predicated on the position that the subject specification does not provide sufficient written description of eukaryotic solubility responsive promoters that could be used in the construction of eukaryotic host cells encompassed by the claims.

Applicants respectively disagree with the reasoning set forth in the instant Office Action. Nevertheless, in order to expedite prosecution of the subject application, Applicants have presently amended the claims to recite only prokaryotic protein solubility promoters. As disclosed in the specification (e.g., the Examples) and also acknowledged in the Office Action, Applicants have provided a reasonable number of representative protein solubility response promoters that are obtained from prokaryotic species, e.g., *E. coli*. It is well known that many stress response genes (e.g., heat shock genes) are structurally and functionally conserved among various prokaryotic species.

In addition, many protein solubility responsive genes and promoters from various prokaryotic species are known in the art at the time the instant application was filed. For example, just like in *E. coli*, many heat shock or stress-responding proteins were also identified in *S. typhimurium* and *Listeria* (see, e.g., Bunning et al., Appl Environ Microbiol. 56: 3216-9, 1990; Engraber et al., Infect Immun. 60: 3072-8, 1992; Mackey et al., J Appl Bacteriol. 69: 373-83, 1990; and Morgan et al., Proc Natl Acad Sci

U S A. 83: 8059-63, 1986). Description of such non-E. coli stress-responding proteins is provided in the specification. For example, the specification (through incorporation by reference of Parsell et al., Nature 372: 475-78, 1994, cited at page 2, line 30 of the specification) disclosed that some heat shock proteins (e.g., Hsp104) are conserved in various species, e.g., from *Saccharomyces cerevisiae* to *Arabidopsis thaliana* to *E. coli*. At least some of these stress-responding proteins are responsive to changes in protein solubility.

Thus, it is clear that the subject specification has provided sufficient description of protein solubility response genes and promoters from prokaryotic species. A skilled artisan would conclude that Applicants had possession of the presently claimed invention to the extent that it encompasses host cells comprising prokaryotic protein solubility promoters not specifically enumerated in the specification. In view of the above claim amendments and reasoning, Applicants respectfully request that the instant rejection be withdrawn.

Conclusion

In view of the foregoing, Applicant believes all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned attorney at 858-812-1539.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'H. Wang', with a large, sweeping flourish extending to the right.

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